

**REMARKS**

Claims 224-292 are pending. By this Amendment, the Specification and claims 224, 228, 229, 232, 234, 235 and 240 are amended. Reconsideration in view of the above amendment and following remarks is respectfully requested.

The courtesies extended to Applicants' representative by Examiner Saucier at the interview held October 22, 2003, are appreciated. The reasons presented at the interview as warranting favorable action are incorporated into the remarks below and constitute the record of the interview.

Entry of the amendments is proper under 37 CFR §1.116 since the amendments: (a) place the application in condition for allowance (for the reasons discussed herein); (b) do not raise any new issue requiring further search and/or consideration (since the amendments amplify issues previously discussed throughout prosecution); (c) satisfy a requirement of form asserted in the previous Office Action; (d) do not present any additional claims without canceling a corresponding number of finally rejected claims; and (e) place the application in better form for appeal, should an appeal be necessary. The amendments are necessary and were not earlier presented because they are made in response to arguments raised in the final rejection. Entry of the amendments is thus respectfully requested.

**I. The Specification Satisfies All Formal Requirements**

The Office Action objects to the specification for introducing new matter into the disclosure. Applicants respectfully disagree with the Examiner's position.

With respect to the insertion of "and/or fluorescent tagged co-polymer" on pages 6, 15, 29 and 30, "or" has been deleted from the specification.

With respect to the insertion on page 21 of "anti-apoptotic agents, and agents that decrease vascular permeability", these features are disclosed in at least claim 143 of the application as originally filed.

With respect to the insertion at line 24 of page 22, this disclosure was provided in at least original claims 137 and 139 of the application as originally filed.

With respect to the insertion at line 30, the disclosure is amended accordingly.

With respect to the insertions on page 24, 25 and 26, support for the insertions can be found at least at original claim 168 of the application as originally filed. Please note the recitation in claim 168 of the second temperature of the second medical fluid between about 10°C and about 24°C recites the features or perfusing the organ at a normothermic temperature.

**II. Claims 224-267 Satisfy the Requirements  
of 35 U.S.C. §112, First Paragraph**

Claims 224-267 are rejected under 35 U.S.C. §112, first paragraph. Applicants respectfully disagree with this rejection.

With respect to claim 224 and the recitation of "energy levels in the organ", these features can be found, for example, on page 21, line 12, page 21, line 25, page 21, line 28, page 22, line 3, page 27, line 31 and claim 44 as originally filed.

With respect to claims 225, 227 and 230, these claims are cancelled.

With respect to claim 232, claim 232 is amended to recite approximately 1°C to approximately 15°C.

Claim 235 is amended to recite "about 20°C."

Claim 240 is amended to recite "the second medical fluid."

With respect to claim 253, claim 180 as originally filed recites that the medical fluid that contains little or no oxygen comprises at least one member selected from anti-oxidants, anti-apoptic agents, and agents that decrease vascular permeability.

Withdrawal of the rejection of claims 224-267 under 35 U.S.C. §112, first paragraph is respectfully requested.

**III. Claims 228 and 251-253 Satisfy the Requirements of 35 U.S.C. §112, Second Paragraph**

Claims 228 and 251-253 are rejected under 35 U.S.C. §112, second paragraph as indefinite. Applicants respectfully disagree with the Examiner's assertions.

With respect to "hypothermic temperature", this term is used throughout the specification and is well defined with respect to what are the metes and bounds of the term "hypothermic" and this term is within the level of one of ordinary skill in the art. For example, on page 30 of the specification, in the hypothermic mode, an organ is perfused with a cooled medical fluid, preferably at a temperature within a range of approximately 1°C to 15°C, more preferably 4 °C to 10 °C, most preferably around 10 °C.

Accordingly, withdrawal of the rejection of claims 228 and 251-253 under 35 U.S.C. §112, second paragraph is respectfully requested.

**IV. The Claims Define Patentable Subject Matter**

Claims 224-245, 248-252 and 258-266 are rejected under 35 U.S.C. 102(b) as anticipated by WO 88/05261 to Owen; claims 246 and 247 are rejected under 35 U.S.C. §103(a) as unpatentable over Owen in view of WO 96/29864; claims 253 and 254 are rejected under 35 U.S.C. §103(a) as unpatentable over Owen in view of Chambers et al.; claims 255 is rejected under 35 U.S.C. §103(a) as unpatentable over Owen; claim 257 is rejected under 35 U.S.C. §103(a) as unpatentable over Owen in view of Ingawall or WO 97/43899; claims 259-266 are rejected under 35 U.S.C. §103(a) as unpatentable over Owen in view of U.S. Patent No. 5,586,438 to Fahy; and claim 267 is rejected under 35 U.S.C. §103(a) as unpatentable over Owen and Fahy, and further in view of Tanner et al. These rejections are respectfully traversed.

None of the applied art teaches, discloses or even suggests perfusing at least one organ with a first medical fluid at a first temperature to at least one of maintain and restore pre-ischemia or pre-hypoxia energy levels in the organ wherein the first temperature is from about 12°C to about 24°C, as claimed in claim 224.

Instead, Owen is directed to an invention which relates particularly to a total organ perfusion system that allows a donor organ to be maintained extra corporeally for an extended period of time. Further, Owen is concerned with maintaining the organ tissue by maintaining a correct electrolyte balance on either side of the cell membrane with a minimum of ATP usage by the organ or tissue. Additionally, Owen discloses that the organs perfused with the methods of Owens, can be changed between normothermic and hypothermic conditions without tissue degradation (ischemia). As such, Owen does not teach or disclose or even suggest perfusing an organ to at least one of maintain and restore pre-ischemia or pre-hypoxia energy levels in the organ. That is, Owen is concerned with controlling ATP usage during perfusion, not maintaining or restoring the pre-ischemia or pre-hypoxia levels.

Additionally, Owen does not disclose perfusing at least one organ with a first medical fluid at a first temperature wherein the first temperature is from about 12°C to about 24°C. The systems and methods of Owen are designed to maintain the appropriate temperature, pressure, oxygen concentration and ph of the nutrient fluid. For example, as discussed on page 20 of Owen, the acceptable ranges for temperature of perfusate for an organ are normothermic 37°C +/- 1°C and hypothermic temperature 4°C to 6°C.

There are two circuits in the apparatus of Owen, one for cooling the electrolyte perfusion below 10°C and the other for maintaining the emulsion perfusion at 37°C. The electrolyte perfusion solution is cooled from refrigerant coils immersed in reservoir 4 and hydrostatic reservoir 7. Fluid passing through the circuit can also be directed into reservoir 6 containing the emulsion perfusion, to cool the temperature of the perfusion if it exceeds 37°C. Sustaining the emulsion perfusion at 37°C is maintained by heating coils immersed in reservoir 3 and thermal regulator 5.

Thus, the apparatus of Owen are concerned with maintaining the temperatures of the fluids at "acceptable ranges". As such, Owen merely discloses perfusing at a normothermic temperature at 37°C + or - 1°C. As such, Owen does not teach, disclose or even suggest perfusing the at least one organ with a first medical fluid at a first temperature to at least one of maintain and restore pre-ischemia or pre-hypoxia energy levels in the organ wherein the first temperature is from about 12°C to about 24°C.

None of the other cited art makes up for the deficiencies of Owen discussed above.

The present application perfuses the organ with medical fluid so that pre-ischemia levels of reserve high energy nuclear type are maintained and/or restored. This feature is not taught, disclosed or even suggested, nor has the Examiner directed the Applicants' attention to a particular disclosure in Owen for the above discussed features of the present application.

Accordingly, withdrawal of the rejection of claims 224, 228-229 and 232-267 under 35 U.S.C. §102 and §103 is respectfully requested.

**V. Conclusion**

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance. Favorable reconsideration and prompt allowance are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,



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Attachment:

Petition for Extension of Time

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